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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/599,352  | 10/18/2007  | Peter Kenneth Graham | 1171/45540/172-PCT-US | 7270             |
| 279   | 7590        | 07/22/2011           | EXAMINER              |                  |
| MARIA E. KITZ<br>CLARK HILL PLC<br>150 NORTH MICHIGAN AVENUE<br>SUITE 2700<br>CHICAGO, IL 60601 |             |                      | LEE, SI               |                  |
|   |             |                      | ART UNIT              | PAPER NUMBER     |
|   |             |                      | 3771                  |                  |
|   |             |                      | NOTIFICATION DATE     | DELIVERY MODE    |
|   |             |                      | 07/22/2011            | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mkitz@clarkhill.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/599,352             | GRAHAM ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | SI LEE                 | 3771                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is responsive to the amendment filed on 4/4/11. As directed by the amendment: Claims 1, 2, 4, 6, 7, and 11 have been amended. Claims 12 and 13 have been cancelled. Claims 14-16 are newly added. Claims 1-11 and 14-16 are presently pending in this application.

### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities: Line 3, "to a a patient" should be re-written as --to a patient--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, line 9, the term "additional passageway" is unclear because a first passageway has not yet been introduced.

Claims 2-9 are rejected on the basis of that being dependent to independent claim 1.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

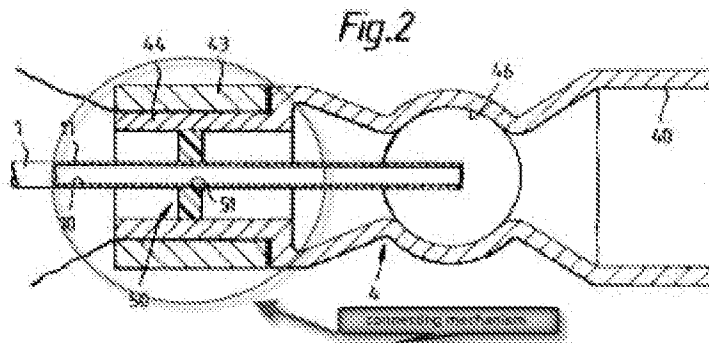
6. Claims 1-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (5,779,687) herein referred to as Bell, in view of Coles et al. (5,513,628) herein referred to as Coles.

Regarding claim 1, Bell discloses a ventilating and aspirating system (see figure 1) having a pressurized source of gas and gases transport means (side ports 45, 46) (column 3 lines 54-57). Figure 1 of Bell shows that the system having a patient connector (41) that is able to deliver the gases to a patient through a tracheotomy tube fitting, a substantially tubular catheter mount (4) being fitted between the patient connector (41) and the gas transport means (45, 46) and having a passageway (extending between elements 44 and 40, see figure 2 of Bell), a suction tube (1) having a distal end and a proximal end, the suction tube (1) being surrounded by a collapsible envelope (2) (flexible, protective sleeve 2, see column 3, lines 16-19). In addition, figure 1 of Bell further shows that the distal end of the tube fitted with a distal connector (33). In column 4, lines 24-26, Bell states that user grips the catheter (1) through the sleeve (2) and pushes it forwardly so that the distal patient end of the catheter is advanced through the connecting member (4) (the proximal end of the suction tube being movable through a proximal connector 43 attached to the envelope). Bell in column 3, lines 42-45, discloses that the proximal connector (43) is releasably connected to the catheter mount (4) (the proximal connector 43 is screwed onto a threaded proximal extension 44

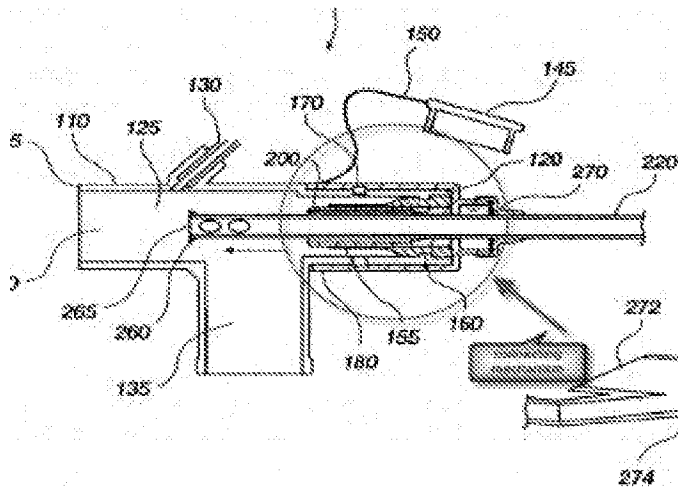
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of the connecting member). Furthermore, Bell in figure 2 further shows that the passageway being covered by a seal 50.

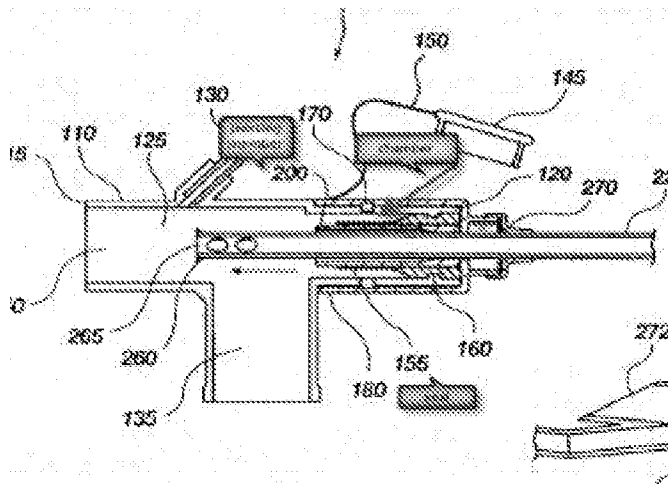
Bell differs from the present invention in that Bell's catheter mount lacks a re-sealing mechanism, and proximal connector (43) lacks a piercing member. However, Coles teaches a ventilating and aspirating system having a catheter mount (105) for connecting with a proximal connector (185), a re-sealable seal (155) (figures 4-6) being located inside the catheter mount (105), the proximal connector having a piercing member (200), and the suction tube is capable of passing through the piercing member (200) and not contacting the seal, see figure 4 of Coles. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bell's catheter mount and proximal connector with a seal having re-sealable mechanism within the catheter mount and a proximal connector having a piercing member as taught by Coles, so as to be able to eliminate contamination of the suction tube.



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**Fig. 4**

Regarding claims 2 and 11, the modified Bell has a chamber abutting an outer surface of the seal (155) and an outer surface of the piercing member (200) and creating a dead space within (see figure 4 of Coles below).



Regarding claim 3, the modified Bell has a proximal connector (180) and a catheter mount (110) connected. The adjacent surfaces on the proximal connector and the catheter mount abut to form a seal (155) (see figure 1 of Coles). When connected, gases are prevented from exiting to the atmosphere (see figure 4 of Coles).

Regarding claim 4, the modified Bell has the catheter mount (110) and the proximal connector (180) releasably connected with a bayonet fitting (see figures 1 and 4 of Coles).

Regarding claim 5, the modified Bell has the seal (155) made of an elastomeric material (column 7 lines 64-66 of Coles). The seal is capable of providing a substantially airtight seal because the seal is airtight until pierced by the piercing member.

Regarding claim 6, the modified Bell has the seal (155) that includes a perforation (157 - aperture) (column 7 lines 66-67). Figures 1 and 4 of Coles show that the perforation allows for the piercing of the seal by the piercing member (200) and resealing the passageway once the proximal connector (180) is detached from the catheter mount (110).

Regarding claim 7, the modified Bell in figure 4 of Coles has the gases transport means which may leak through the seal once pierced (200) and then contained within the dead space.

Regarding claim 8, the modified Bell has the catheter mount allowing the suction tube (220, see figure 4 of Coles) through and entering the tracheostomy fitting (42 - trach tube of Bell, see figure 1) without the suction tube (220) contacting the internal walls of the catheter mount (see figure 4 of Coles).

Regarding claim 9, the modified Bell has the proximal connector (180) which includes a washer (230 – wiper seal) to wipe the suction tube (220) when removed (column 8 lines 59-62).

Regarding claim 14, the modified Bell has at least three passageways and wherein one passageway includes a resealing mechanism (see figures 1 and 4 of Coles). Figures 1 and 2 of Bell show a catheter mount having a first passageway (opening at element 4), a second passageway (45 - port) and a third passageway (opening at element 44).

***Claim Rejections - 35 USC § 102 & 35 USC § 103***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by Lampropoulos et al. (6,287,280) or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Lampropoulos et al. (6,287,280).

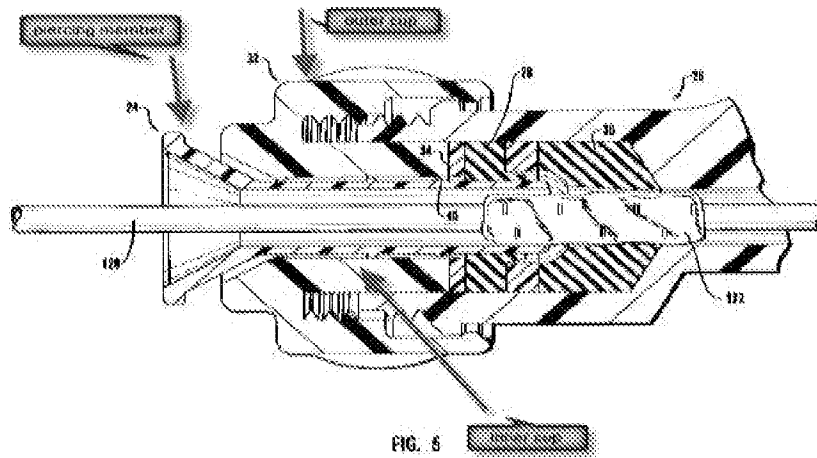
Regarding claim 15, figure 5 of Lampropoulos shows an adapter (10) (connector) having an outer cup-shaped fitting (32), an inner cup shaped fitting nested within the outer cup shaped fitting, and an introducer (24) (piercing member) nested within the inner cup shaped fitting. Figure 5 of Lampropoulos shows the rim of the outer cup



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shaped fitting is longer than the inner cup shaped fitting while the piercing member (24) is longer than the rim of the outer cup shaped fitting. The connector is adapted to be releasably connected to a passageway covered by a seal (28) such that the inner cup shaped fitting abuts the end of the passageway (34) and the piercing member pierces the seal when a connection is formed (column 9 lines 19-28).

Lampropoulos in figures 2 and 5 shows that the connector allows an elongated instrument (120) to pass through the introducer (24) and into the catheter mount passageway formed by elements (28, 30, 34), and the elongated instrument (120) fits snugly within the introducer. Lampropoulos has all the structure as claimed. Note it appears that the suction tube is not part of the invention. Patentable weight will not be given to intended use. Even if the suction tube is part of the invention, however, the feature of introducing a particular instrument such as a suction tube into the body is considered as an obvious design choice since a suction tube is a well known instrument and it appears that Lampropoulos' connector would perform equally well with a suction tube.



Regarding claim 16, Lampropoulos has an outer cup shaped fitting (32) that is fitted with a releasable lockable bayonet fitting (column 8 lines 54-63).

### ***Response to Arguments***

10. Applicant's arguments, see page 6, paragraph 2, lines 2-3, of Applicant's Arguments/Remarks filed on 4/4/11, with respect to the rejection(s) of claim(s) 1-11 under claim rejections 35. U.S.C 102 and 35 U.S.C 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art references to meet the claim limitations presented in the Amendment to the Claims.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Elkins (2001/0044600), lund et al. (5,598,840) and Lorenzen et al. (5,715,815) are cited to show additional suction catheter systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SI LEE whose telephone number is (571)270-5450. The examiner can normally be reached on Monday-Friday 8:30am-6pm, working alternating Friday's.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/SI LEE/

Examiner, Art Unit 3771

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772

For SPE Justine Yu